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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/030,497

06/27/2002

John C. Reed

066654-0704

2174

41552 7590 03/26/2010  
MCDERMOTT, WILL & EMERY  
11682 EL CAMINO REAL  
SUITE 400  
SAN DIEGO, CA 92130-2047

EXAMINER

SANG, HONG

ART UNIT

PAPER NUMBER

1643

NOTIFICATION DATE

DELIVERY MODE

03/26/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

SIP\_Docket@mwe.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/030,497	<b>Applicant(s)</b> REED, JOHN C.	
	<b>Examiner</b> HONG SANG	<b>Art Unit</b> 1643	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 February 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 89,90,92,95-101,103 and 106-117 is/are pending in the application.
- 4a) Of the above claim(s) 111-113 and 115-117 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 89,90,92,95-101,103,106-110 and 114 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                        |                                                                   |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/3/10</u> .                                                  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

#### **RE: Reed**

1. Applicant's response filed on 2/3/2010 is acknowledged. Claims 89, 90, 92, 95-101, 103, and 106-117 are pending. Claims 1-88, 91, 93, 94, 102, 104, and 105 have been cancelled. Claims 111-113 and 115-117 have been withdrawn from consideration as being drawn to non-elected inventions. Claims 89 and 99 have been amended.
2. Claims 89, 90, 92, 95-101, 103, 106-110 and 114 are under examination.
3. The examiner corrects a typographical error made in the office action mailed on 8/6/2006. The date "7/7/2002" should be "7/7/2000" (see page 4, paragraph 5, line 12 which should be "7/7/2000).
4. In the claim listing, the status of claims 89 and 99 is incorrect. The correct status is (currently amended).

#### ***Information Disclosure Statement***

5. The information disclosure statement (IDS) filed on 10/22/2002 has been considered. A signed copy is attached hereto.

#### ***Rejections Withdrawn***

6. The rejection of claims 89-110 and 114 under 35 U.S.C. 103(a) as being unpatentable over Froesch et al. (Proceedings of the American Association for Cancer Research Annual Meeting, March, 1998, 89: 13, print) in view of the teachings of Takayama et al. (Cancer Research 1998, 58: 3116-3131, IDS), Noordzij et al. (J.

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Urology, 1997, 158: 1880-1885) and Sano et al. (US patent NO. 5,665,539, IDS) is withdrawn in view of applicant's amendment to the claims.

***Rejections Maintained***

***Claim Rejections - 35 USC § 103***

7. The rejection of claims 89, 90, 92, 95-101, 103, 106-110 and 114 under 35 U.S.C. 103(a) as being unpatentable over Froesch et al. (Proceedings of the American Association for Cancer Research Annual Meeting, March, 1998, 89: 13, print) in view of the teachings of Tang et al. (J. Clin. Oncology, 1999, June, 17(6): 1710-1719, IDS), Yawata et al. (Oncogene, 1998, 16:2681-2686, IDS), and Sano et al. (US patent NO. 5,665,539, IDS) is maintained.

The response states that the disclosure of Froesch et al., at best, describes BAG-1L expression in prostate cancer. Tang et al. appear to disclose that BAG-1 did not correlate with conventional prognostic factors and that nuclear expression of BAG-1 tended to be associated with a shorter disease free and overall survival in invasive breast cancer (see abstract and Figure 4). One of skill in the art would have no motivation to combine the description in Froesch et al. of the expression of BAG-1L in prostate cancer with the description of Tang et al. expression of nuclear expression of BAG-1 in breast cancer to achieve the claimed methods. There would be no expectation of success because Tang et al. discloses that the nuclear expression of BAG-1 correlates with shorter disease free and overall survival (see abstract and Figure 4), whereas the claimed methods compare the patients cytosolic BAG-1 protein level to a

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reference BAG-1 gene expression level, wherein the reference BAG-1 gene expression level being a level of BAG-1 gene expression above which correlates with decreased survival and below which correlates with increased survival.

Applicant's arguments have been carefully considered but are not persuasive. Froesch et al. teach that BAG-1 protein is expressed in all 9/9 prostate cancer cell lines and 51/51 archival prostate tumor specimens (emphasis added). It is noted that BAG-1 protein (RAP46) is cytosolic BAG-1. Furthermore, at the time the instant invention was made, the expression of cytosolic BAG-1 protein in prostate cancer was known in the prior art, as evidenced by Takayama et al (Cancer Research 1998, 58: 3116-3131, IDS). Takayama discloses that BAG-1 (cytosolic) is expressed in seven prostate cancer cell lines and is expressed at higher level than BAG-1L (nuclear protein) (see Table 2). Tang et al. stated "BAG-1 is overexpressed in the majority of invasive breast carcinoma. Although BAG-1 did not correlate with conventional prognostic factors, its overexpression, especially the nuclear expression, may be associated with shorter disease-free and overall survival" (see abstract). Tang et al. disclose that in multivariate analysis, BAG-1 expression was significantly associated with shorter disease-free and overall survival (see abstract). It is noted that in Tang's reference the expression of BAG-1 is either cytoplasmic BAG-1 expression or nuclear BAG-1 expression because of the 140 breast carcinomas examined for BAG-1 expression, only two (1.4%) had both nuclear and cytoplasmic expression, 26 breast carcinomas (18.2%) had the nuclear staining pattern, and 80 (57.1%) had cytoplasmic staining pattern, (see page 1712, last paragraph). Tang et al. detected two patterns of BAG-1 expression in breast cancer,

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cytosolic and nuclear, and further correlated the presence or absence of BAG-1 expression, its staining intensity and its subcellular localization with disease-free and overall survival (see page 1711, column 2, paragraph 1, page 1712, last paragraph, page 1713 and Figure 4). Given the teachings of Froesch that both cytosolic and nuclear BAG-1 proteins were expressed in prostate cancer, the teachings of Tang and Yawata that overexpression of BAG1 enhances cancer cell metastasis, and the teachings of Tang that overexpression BAG-1 protein (either cytosolic or nuclear protein) may be correlated with a shorter disease-free and overall survival in breast cancer, one skilled in the art would have been motivated to determine the prognostic function of both cytosolic and nuclear BAG-1 protein in prostate cancer. One skilled in the art would have had a reasonable expectation of success because Froesch et al have detected BAG-1 protein in all 9/9 prostate cancer cell lines and all 51/51 prostate tumor specimens, Tang et al. have shown that in multivariate analysis, BAG-1 expression was significantly associated with shorter disease-free and overall survival (see abstract, Figures 3 and 4), and Yawata et al. have shown that overexpression of BAG-1 has been shown to increase the metastatic potential of tumor cells *in vivo*. For the forgoing reasons, the rejection is deemed proper and is therefore maintained.

### **Conclusion**

8. No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to HONG SANG whose telephone number is (571)272-8145. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Hong Sang/  
Examiner, Art Unit 1643

/Larry R. Helms/  
Supervisory Patent Examiner, Art Unit 1643